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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,222	06/17/2005	Geoffrey Philip Dobson	FREE 1150	4568
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SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			EXAMINER MACAULEY, SHERIDAN R	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 01/02/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

Office Action Summary

Application No.

10/539,222

Applicant(s)

DOBSON, GEOFFREY PHILIP

Examiner

Sheridan R. MacAuley

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-36 and 38-45 is/are pending in the application.
- 4a) Of the above claim(s) 30 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 31, 32, 35, 36 and 38-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/11/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received and entered on October 18, 2007.

Claims 1-25 and 37 are cancelled. Claims 26-36 and 38-45 are pending.

Election/Restrictions

1. Applicant's election of species in the replies filed on October 5, 2007 and October 18, 2007 is acknowledged. Applicant elected an opioid as an additional component, a myocyte as the specific cell, tissue or organ and ionic magnesium as the additional agent. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and the requirement for restriction is therefore made FINAL.
2. Claims 30 and 33-35 recite specific additional components which are not the additional component that was elected, i.e. an opioid. Thus, claims 30 and 33-35 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim.
3. Claims 26-29, 31, 32, 35, 36 and 38-45, to the extent that they read upon the elected species, are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 40 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The term "blood-based" renders claim 40 indefinite. It is unclear whether applicant intends for the composition to comprise a component derived from blood, to be based on the chemical composition of blood, or some other alternative.
7. Claims 41 and 42 are indefinite insofar as they depend from claim 40.
8. Claim 45 provides for the use of a composition or medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
10. Claim 45 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under

35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 26-29, 31, 32, 35, 36 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien (US 5,656,420, 1997) in view of Berdyaev et al. (US 5,432,053) and Chien (Journal of Thoracic and Cardiovascular Surgery, 1994, 107:965-967). Claim 26 recites a method for reducing electrical disturbance of a cell's resting membrane potential comprising administering to the cell an effective amount of a composition comprising an effective amount of a local anaesthetic and an opioid. Claim 27 recites a method for reducing damage to a cell, tissue or organ following ischaemia comprising administering to the cell, tissue or organ an effective amount of a

composition comprising an effective amount of a local anaesthetic and and an opioid.

Claim 28 recites a method for preconditioning a cell or tissue during ischaemia or reperfusion comprising administering an effective amount of a composition comprising an effective amount of a local anaesthetic and an opioid. Claim 29 recites a method for reducing damage to a cell, organ or tissue before, during and following a surgical or clinical intervention comprising administering to the cell, organ or tissue an effective amount of a composition comprising an effective amount of a local anaesthetic and an opioid. Claims 31 and 32 recite a method according to claim 27 wherein the opioid is selected from enkephalins, endorphins and dynorphins, preferably an enkephalin which targets delta, kappa and/or mu receptors, specifically a delta opioid receptor agonist. Claim 36 recites a method according to claim 27 wherein the cell is a myocyte. Claim 38 recites a method according to claim 27 wherein the composition further comprises ionic magnesium. Claim 39 recites a method according to claim 27 wherein the composition has been oxygenated. Claim 40 recites a method according to claim 27 comprising administering the composition as part of a medicament including the composition and a blood-based or crystalloid carrier. Claim 41 recites a method according to claim 40 wherein the medicament has concentrations of one or more of sodium, calcium and chloride lower than physiological concentrations. Claim 42 recites a method according to claim 40 wherein the medicament has concentrations of one or more of sodium, calcium and chloride that have been adjusted from blood physiological concentrations. Claim 43 recites a method according to claim 27 wherein the composition is at a temperature of profound hypothermia (0 to 4 degrees Celsius),

moderate hypothermia (5 to 20 degrees Celsius), mild hypothermia (20 to 32 degrees Celsius) or normothermia (32 to 38 degrees Celsius). Claim 44 recites a method according to claim 27 wherein the components of the medicament or composition are combined before administration or when the components are administered substantially simultaneously or co-administered. Claim 45 recites the use of a composition or medicament according to claim 27 for treatment of a subject in need thereof.

14. Chein (1997) teaches a method for extending the survival time of mammalian lung tissue comprising administering to the tissue a composition comprising an opioid, DADLE, which is an enkephalin and a delta opioid receptor agonist (abstract). Chein (1997) teaches that organ preservation solutions may comprise ionic magnesium (see table in col. 6-7). Chein (1997) teaches that, during perfusion, the preserved tissue and solution was ventilated (i.e. exposed to oxygen, col. 4, lines 64-67). The composition used by Chein (1997) comprises concentrations of ions which are similar to that of a blood-based solution, and contains no calcium, thus the calcium concentration has been adjusted from and is lower than physiological concentrations (col. 7-8). The composition used by Chein (1997) is at a temperature of profound hypothermia and the components are combined before administration (abstract, col. 4, lines 13-40). The teachings of Chein (1997) are directed to the treatment of a subject in need of the treatment (col. 2, line 45-col. 3, line 21). Chein (1997) does not teach that the composition comprises an anesthetic or that the cells which are treated are myocytes.

15. Berdyaev teaches a method for preservation of living tissues by the use of a solution comprising an anesthetic (col. 1, line 60-col. 2, line 38). Berdyaev teaches that

the composition is suitable for the preservation of heart tissue, which comprises myocytes (see col. 3, example 1).

16. Chien (1994) teaches that compositions comprising DADLE are suitable for preservation of many different types of tissues, including heart tissues (p. 965, col. 2-p. 966, col. 2).

17. At the time of the invention, a method for the preservation of tissues or cells comprising nearly all of the claimed elements was known, as taught by Chien (1997). Further, methods were known at the time of the invention for using similar compositions to preserve heart tissue and that such compositions could comprise an anesthetic, as taught by Chien (1994) and Berdyaev, respectively. Motivation to combine these teachings is provided by Berdyaev, who teaches that anesthetics are desirable additions to such compositions because they are useful for stabilization of membranes (col. 2, lines 28-30). Further, one would have been motivated to use the method of Chein (1997) for the preservation of tissues other than lung tissue, including heart tissues, because Chein (1994) teaches that compositions comprising DADLE could be used for the preservation of such tissues. The combined method of the cited references would inherently perform all of the functions recited in claims 26-29 because it comprises the claimed method step, i.e. administration of an effective amount the composition recited in the claims. One of ordinary skill in the art would have had a reasonable expectation of success in combining these teachings because all of the teachings are directed to the preservation of the claimed tissues, and thus all of the components in the compositions are suitable for such methods. Therefore, one of

ordinary skill in the art would have had a reasonable expectation of success in combining the teachings discussed above to arrive at the claimed invention.

18. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651